Final Rule Material:
Secondary Research with Identifiable Information and Biospecimens

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CITI Program Final Rule Materials

- We invite you to use this presentation to introduce those involved in the research enterprise to the changes to the federal Common Rule made by the Final Rule published by the U.S. Department of Health and Human Services (HHS) in 2017.
- All CITI Program Final Rule materials are available on the "Resources" tab of the CITI Program website, www.citiprogram.org/en/resources.
- **Note**: These resources are based on the Final Rule issued by the U.S. Department of Health and Human Services (HHS) at 45 CFR 46, Subpart A - "Federal Policy for the Protection of Human Subjects" (the Common Rule) on 19 January 2017. These resources have been updated to reflect the 19 June 2018 Final Rule. The general compliance date is now 21 January 2019.

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Secondary Research with Identifiable Information and Biospecimens

- This presentation will review options for conducting secondary research under the revised Common Rule (the Final Rule).
- The "Federal Policy for the Protection of Human Subjects: Six Month Delay of the General Compliance Date of Revisions While Allowing the Use of Three Burden-Reducing Provisions During the Delay Period" delayed the general compliance date until 21 January 2019 (HHS 2018).

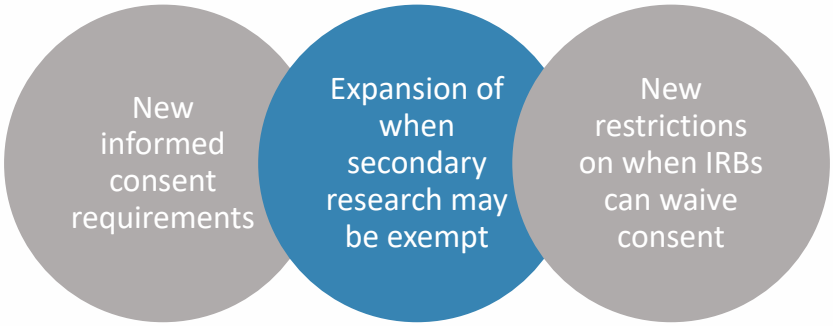
What is secondary research?

Secondary research is a general term typically describing research projects using information or biospecimens for some other purpose after the primary research or clinical intervention used to collect them.

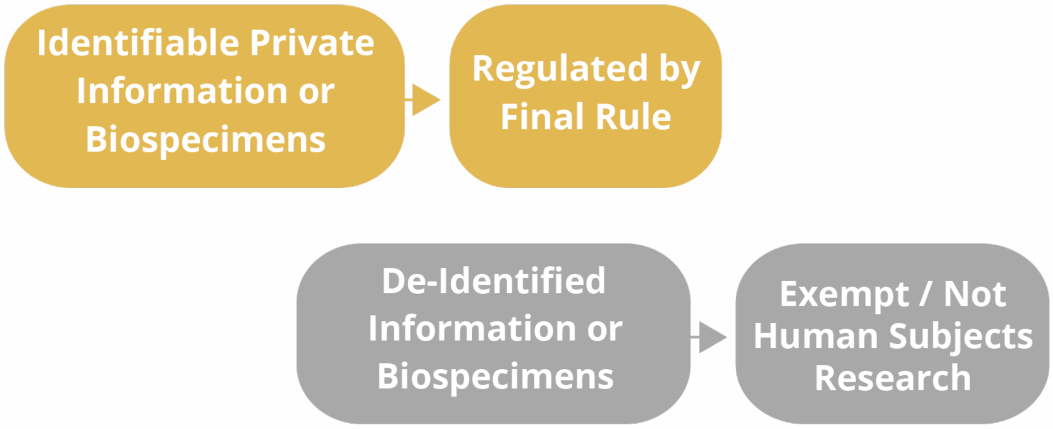
- *Initial collection may come through a separate research study or non-research activity (for example, clinical care).*

What is new in the Final Rule?

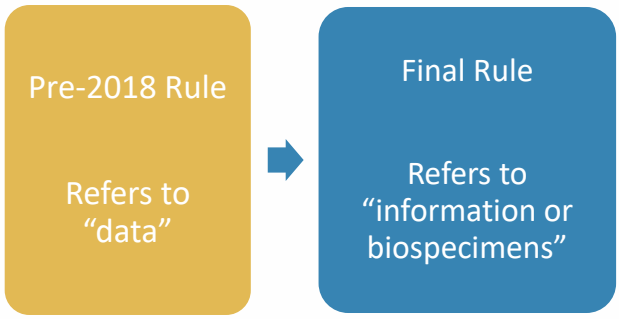
- The revisions to the Common Rule made by the Final Rule affect how secondary research involving identifiable private information or identifiable biospecimens may be conducted.



Under the Final Rule



Revised "Human Subject" Definition



- The Final Rule 46.102(e) revised the definition of "human subject."
  - *This language change was necessary to present contemporary language reflecting current practice (Final Rule Preamble).*
  - *The new language has similar effect as the previous language.*

Final Rule Secondary Research Options

How can secondary research with identifiable private information or identifiable biospecimens be conducted under the Final Rule?

Action	Explanation
Make the Information or Biospecimens Non-Identifiable	No substantive change from current practice; secondary use of non-identifiable information or biospecimens is still exempt from the Final Rule.
Obtain IRB Approval for Research with an IRB Waiver of Consent	Same practice in the Final Rule as currently exists under pre-2018 rule with waiver per 46.116(d); however, there are some new limits on when IRBs can waive consent.
Obtain IRB Approval for Research with Prospective Consent from Subjects	Only change from current practice is that the Final Rule requires informed consent forms to include new required language about secondary use of information or biospecimens.
NEW Use the Broad Consent Option	For secondary research use of identifiable information or biospecimens.
UPDATED Make Use of Expanded Exemption 4 Criteria	For instance, secondary research projects where the identifiable information is protected under Health Insurance Portability and Accountability Act (HIPAA) requirements now may qualify as exempt from the Final Rule.

Secondary Research Option 1: Research Using Non-Identifiable Information or Biospecimens

- No change from pre-2018 (current) Common Rule.
  - *Non-identifiable information or biospecimens do not meet definition of "human subject" under 46.102(e).*
  - *Research not subject to the Common Rule – no IRB review required.*
- For more information about research involving coded private information or biological specimens, refer to the Office for Human Research Protections (OHRP) Guidance on Coded Private Information or Specimens in Research (2008).

Secondary Research Option 2: Research Approved by IRB with Waiver of Consent

- Similar to pre-2018 (current) Common Rule.
  - *Researcher uses identifiable information or biospecimens collected for another purpose and requests a waiver of consent from the IRB.*
  - *IRB review required (typically through expedited review).*
- **NEW** IRBs must make one new waiver finding under 46.116(f)(3)(iii).
- **NEW** IRBs may not waive consent if subjects declined future use of their identifiable information or biospecimens through the broad consent process.
- **NEW** Limited requirements for IRB continuing review if project approved through expedited review.

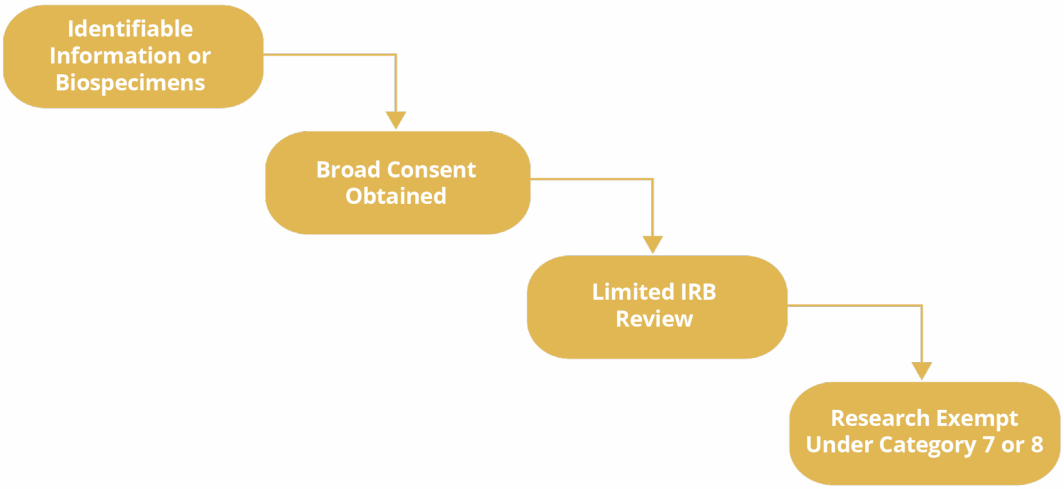
Secondary Research Option 3: Research Approved by IRB with Consent

- Similar to pre-2018 (current) Common Rule.
  - *Researcher obtains consent from subjects for secondary use of their identifiable information or biospecimens.*
  - *IRB review required (typically through expedited review).*
- **NEW** Consent must meet new requirements under 46.116.
  - *New language about secondary use of information or biospecimens.*
- **NEW** Limited requirements for IRB continuing review if project approved through expedited review.

Secondary Research Option 4: Expanded Exempt Category 4

- Similar to pre-2018 (current) Common Rule.
- **EXPANDED** Exempt category 4 (46.104[d][4]) does not require consent for secondary research if certain criteria are met, including if the information or biospecimens are either:
  - *Publicly available.*
  - *Not readily identifiable or directly linked to subjects by identifiers.*
  - ***NEW** Subject to HIPAA protections (can remain identifiable) for certain research.*
  - *Government-generated or government-collected for nonresearch activities.*
- **NEW** Expanded exempt category 4 does not require the identifiable information or biospecimens to be existing for secondary research.

New Exempt Categories 7 & 8



Secondary Research Option 5: New Exempt Category 7

- **New** exempt category 7 (46.104[d][7]) allows for storage or maintenance for secondary research for which broad consent is required.
  - ***NEW*** *Limited IRB review required to confirm the proposed project conforms to parameters of the broad consent for future secondary use of identifiable information or biospecimens including:*
    - *Broad consent was obtained and documented [or waiver of documentation].*
    - *Adequate provisions in place to protect privacy and confidentiality if there is a change made for research purposes in how data are stored or maintained.*
    - *Secondary research is within scope of broad consent.*

Secondary Research Option 6: New Exempt Category 8

- **New** exempt category 8 (46.104[d][8]) allows for secondary research that uses identifiable information and biospecimens obtained under the new broad consent process.
  - ***NEW*** *Limited IRB review required to confirm the proposed project conforms to parameters of the broad consent for future secondary use of identifiable information or biospecimens including:*
    - *Broad consent was obtained and documented [or waiver of documentation].*
    - *Secondary research is within scope of broad consent.*
    - *Investigator may not return individual results back to subject unless required by law.*

Additional Requirements

- Institutions may have additional requirements and expectations beyond the Final Rule requirements.
- Investigators must check with their institutions to determine local requirements such as state law or institutional policy.

References

- U.S. Department of Health and Human Services (HHS). 2017. “Federal Policy for the Protection of Human Subjects.” *Federal Register* 82(12):7149-274.
- U.S. Department of Health and Human Services (HHS). 2018. “Federal Policy for the Protection of Human Subjects: Six Month Delay of the General Compliance Date of Revisions While Allowing the Use of Three Burden-Reducing Provisions During the Delay Period.” Federal Register 83(118):28497-520.